

## REMARKS

### 1. Preliminary Remarks

#### a. Status of the Claims

Claims 31, 32, and 39-42 are pending in this application. Claims 1-30, 33-38 have been previously canceled without prejudice. Claims 39-42 are amended. Applicant respectfully requests entry of the amendments, and remarks made herein into the file history of the application. Upon entry of the amendments, claims 31, 32 and 39-42 will be pending and under active consideration.

#### b. Amendment to the Claims

Claims 39 and 40 have been amended to be directed to a vector comprising a human insert, wherein the human insert consists of the nucleic acid of claim 31 or 32. Claims 41 and 42 have been amended to be directed to a probe comprising a human insert, wherein the human insert consists of the nucleic acid of claim 31 or 32. Support for claims 39-42 can be found throughout the specification, for example, paragraphs 0043-0045. Applicant submits that one of ordinary skill in the art would recognize that features other than the human insert consisting of the nucleic acids of either 31 or 32 would be necessary for a functional vector or for identifying whether the probe bound to a complementary sequence.

#### c. Amendment to the Specification

On pages 3 and 4 of the Office Action, the Examiner asserts that the application contains disclosure entirely outside the bounds of the allowed claims. The Examiner further asserts that the Applicant is required to modify the brief summary of the invention as well as amend the specification to include all descriptive matter pertinent to SEQ ID NOS: 15 and 6527. The Examiner further requests that the additional disclosure from Tables 1-11 that do not relate to SEQ ID NO: 15 and 6527 be removed.

Applicant has amended the Summary of the Invention to be in harmony with the claims. The Detailed Description has also been amended to include all descriptive matter pertinent to SEQ ID NOS: 15 and 6527 from Tables 1 through 11 after paragraph 0151. Support for the text after 0151 can be found in Table 1, line 724; Table 2, lines 6980-7077; Table 3, line 146; Table 4, lines 447-454, Table 5, line 166; Table 6, lines 1642-1674, 1938-1976, 4042-4298, 5306-5324, and 5744-5790; Table 7, lines 1468-1501; Table 8, lines 7124-7276; Table 9, lines 14949-15217; and Table 11 lines 3-19. Finally, the description added after the title "Detailed Description" can be found in the originally filed Summary of Invention. Applicant respectfully submits that no new matter has been

introduced through these amendments and submits that the specification is in compliance with 37 C.F.R. 1.52(e)(5). In view of the foregoing amendments, Applicant respectfully request that the objection to the specification be withdrawn.

## 2. Patentability Remarks

### a. 35 U.S.C. §102(e), Tuschl

On pages 5-7 of the Office Action, the Examiner rejects 32, 40 and 42 under 35 U.S.C. §102(e) as being anticipated by Tuschl *et al.*, WO03/029459. Specifically, the Examiner asserts that Tuschl teaches a 22-mer mature mouse miRNA (miR-151) as set forth in SEQ ID NO: 179 (hereafter “miR-151”). The Examiner alleges that the asserted sequence of miR-151 differs by two nucleotides (20/22~90.9%) from Applicants claimed human miR as set forth in SEQ ID NO: 15. The Examiner also asserts that Tuschl teaches variants of miR-151 that are 19-24 nucleotides in length and can be at least 80%, 90%, 95% or 99% identical to miR-151 or its complement. The Examiner concludes that one of skill would instantly recognize each 22-nucleotide sequence 80% and 90% identical or complementary to the miR-151 including instantly claimed SEQ ID NO: 15. Applicant respectfully disagrees with the legal basis of the rejection.

The Applicant respectfully submits that the Examiner has not made a prima facie of anticipation because the Examiner has failed to show that each and every element of the claimed invention is taught expressly or inherently in Tuschl. Instead, the Examiner used various teachings of Tuschl to construct a genus of sequences. Importantly, Tuschl does not teach the sequence of the nucleic acid species of claim 32. As a general rule, a genus does not anticipate a claim to a species within a genus. The exception to this rule is when the genus is small. (*See Bristol-Myers Squibb Co. v. Ben Venue Laboratories Inc.*, 246 F.3d 1368 (Fed. Cir. 2001)).

The genus constructed by the Examiner from Tuschl, however, is extremely large. The mature miRNAs (*e.g.*, miR-151) of Tuschl are taught to be 19-24 nucleotides in length on page 3, lines 17 and may further be an 80%, 90%, 95% or 99% variant of miR151 as taught on page 43, lines 11, 19, and 20 as well as page 2, line 14 of Tuschl. Solely focusing on 90% variants of miR151 presents to one of skill over  $7.50 \times 10^3$  choices.<sup>1</sup> This is only a small fraction of the total number of species in the genus of Tuschl when considering the other length and percent identity species contemplated for miR151. Accordingly, claim 32 is not anticipated by Tuschl. In view of the

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<sup>1</sup> The number of different 22-mers that would be at least a 90% variant is as follows: A two base variant accounts for  $(22 \times 4)(21 \times 3)$ . A one base variant is  $(22 \times 4)$ . No variant is the 22 mer.  $(22 \times 4)(21 \times 3) + (22 \times 4) + 22 = 7502$

foregoing remarks, Applicant submits that the rejection of claims 32, 40 and 42 under 35 U.S.C. §102(e) as being anticipated by Tuschl is overcome and should be withdrawn.

**b. 35 U.S.C. §102(e), Venter**

On page 7 of the Office Action, the Examiner rejects claims 39-42 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,812,339 (hereafter “Venter”). The Examiner asserts that Venter teaches a 346, 112 SNP-containing nucleic acid sequence comprising the instantly claimed SEQ ID NOS: 6527 and 15. The Examiner alleges that Venter further taught DNA and RNA vectors containing the SNP-containing nucleic acid. The Examiner further asserts that the vector/probe claims do not exclude additional unrecited heterologous sequence adjacent or contiguous with SEQ ID NOS: 15 and 6527 and therefore is anticipated by Venter. Applicant respectfully disagrees.

In order to expedite prosecution, however, Applicant has amended claims 39-42 to delete the term “heterologous” and use the phrase “the human insert consists of the nucleic acid of claims 31 or 32” in support in paragraph 0043 for the vectors and probes in the specification. Specifically, paragraph 0043 states “the vectors comprising the DNAs” and the “probes comprising the DNAs.”<sup>2</sup> The DNA is a nucleic acid comprising the claimed nucleic acids of claim 31 or 32. The vector of Venter contains an insert that is 346,112 nucleotides in length. Thus, the Venter insert is far longer than the inserts required in the vector and probe claims 39-42, and therefore do not meet the claimed length limitations. Furthermore, none of the cited §102 references teach or suggest any insert except for the Venter insert of 346,112 nucleotides. In view of the foregoing amendment and remarks, the Applicant respectfully submits that the rejection of claims 39-42 under 35 U.S.C. §102(e) over Venter has been overcome and requests that the rejection be withdrawn.

**c. 35 U.S.C. §102(b), Zhou**

On pages 8 and 9 of the Office Action, the Examiner rejects claims 40 and 42 under 35 U.S.C. §102(b) as being anticipated by GenBank Accession No. AQ420078 (hereafter “Zhao”). Specifically, the Examiner asserts that Zhao teaches a 684 nucleotide DNA comprising the sequence set forth in SEQ ID NO: 15. The Examiner asserts Zhao teaches a vector comprising the 684 insert

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<sup>2</sup> [0043] Accordingly, the invention provides several substantially pure nucleic acids (e.g., genomic DNA, cDNA or synthetic DNA) each comprising a novel GAM oligonucleotide, vectors comprising the DNAs, probes comprising the DNAs, a method and system for selectively modulating translation of known target genes utilizing the vectors, and a method and system utilizing the GAM probes to modulate expression of GAM target genes.

and a probe would be indistinguishable from the vector. The Examiner concludes Zhao anticipates the vector/probe claims 40 and 42. Applicant respectfully disagrees.

Similar to the discussion above for Venter, the Zhao insert is far longer than the inserts required in the vector and probe claims 40 and 42, and therefore do not meet the claimed length limitations. Furthermore, none of the cited §102 references teach or suggest any insert except for the Zhao insert of 684 nucleotides. In view of the foregoing amendment and remarks, the Applicant respectfully submits that the rejection of claims 40 and 42 under 35 U.S.C. §102(b) over Venter has been overcome and requests that the rejection be withdrawn.

### 3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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Dated: November 23, 2009

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